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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/045,677	01/15/2002	Deane Louis Falcone	50229-295	2298

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EXAMINER

KRUSE, DAVID H

ART UNIT PAPER NUMBER

1638

DATE MAILED: 12/03/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/045,677

Applicant(s)

FALCONE ET AL.

Examiner

David H Kruse

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 08 September 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-4 and 6-25 is/are pending in the application.
- 4a) Of the above claim(s) 14-25 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-4 and 6-11 is/are rejected.
- 7) ☒ Claim(s) 12 and 13 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 08 September 2004 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date 09/08/2004.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

STATUS OF THE APPLICATION

1. This Office action is in response to the Amendments and Remarks filed 8 September 2004.
2. The Information Disclosure Statement filed on 8 September 2004 has been considered, a signed copy is attached hereto.
3. Applicant has clarified the issue concerning the objection to claim 11 for provisional double patenting over claim 10, on page 11 of the response. The objection is withdrawn.
4. Those rejections or objections not specifically addressed in this Office action are withdrawn in view of Applicant's amendments or response.
5. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Election/Restrictions

6. Claims 14-25 remain withdrawn from further consideration pursuant to 37 CFR § 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on 1 April 2004.
7. This application contains claims 14-25 drawn to an invention nonelected with traverse in the reply filed on 1 April 2004. A complete reply to the final rejection must include cancellation of nonelected claims or other appropriate action (37 CFR § 1.144) See MPEP § 821.01.

Drawings

8. The drawings filed 8 September 2004 are objected to by the Examiner. Color photographs and color drawings are acceptable only for examination purposes unless a petition filed under 37 CFR § 1.84(a)(2) is granted permitting their use as acceptable drawings. In the event that applicant wishes to use the drawings currently on file as acceptable drawings, a petition must be filed for acceptance of the color photographs or color drawings as acceptable drawings. Any such petition must be accompanied by the appropriate fee set forth in 37 CFR § 1.17(h), three sets of color drawings or color photographs, as appropriate, and, unless already present, an amendment to include the following language as the first paragraph of the brief description of the drawings section of the specification:

The patent or application file contains at least one drawing executed in color. Copies of this patent or patent application publication with color drawing(s) will be provided by the Office upon request and payment of the necessary fee.

Color photographs will be accepted if the conditions for accepting color drawings have been satisfied.

Claim Objections

9. Claim 12 is objected to because of the following informalities: Claim 12 appears to contain a typographical error and reads as dependent upon claim 15, a non-elected invention, but it appears that Applicant intended to change the dependency from claim 5 to claim 1. Appropriate correction is required. Please also note that at claim 5, the indication "Currently cancelled" should simply be -- Cancelled --.

Claim Rejections - 35 USC § 112

10. Claims 10 and 11 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The instant claims are indefinite because the nicotinic acetylcholine agonist or antagonist appears to mean a nicotinic acetylcholine receptor agonist or antagonist, because the radioligand binds to the receptor, not to the compound that is naturally bound by the receptor. Appropriate correction is required.

11. The following is a quotation of the first paragraph of 35 U.S.C. § 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

12. Claims 1-4 and 6-9 are rejected under 35 U.S.C. § 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter, which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The instant claims are directed to a method of identifying plant genetic material comprising analyzing plant cells by at least one radioligand displacement assay, wherein Applicant only describes one radioligand displacement assay, that being for a nicotinic acetylcholine receptor (pages 17-19 of the specification). Applicant does not describe other radioligand displacement assays that would be required to practice the claimed method, in particular assays directed to "metabolites of interest having pharmacological properties". Hence, it is unclear from the instant specification that

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Applicant was in possession of the invention as broadly claimed. A method is not described if products used in the method are not described. See 64 Fed. Reg. 71427, 71428 (1999), comment No. 4.

13. Claims 1-4 and 6-9 are rejected under 35 U.S.C. § 112, first paragraph, because the specification, while being enabling for a method of identifying plant genetic material comprising analyzing cells by a radioligand displacement for a nicotinic acetylcholine receptor, does not reasonably provide enablement for a method of identifying plant genetic material comprising analyzing cells by a radioligand displacement for any metabolite as broadly claimed. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

The instant claims are directed to a method of identifying plant genetic material comprising analyzing plant cells by at least one radioligand displacement assay, wherein Applicant only teaches one radioligand displacement assay, that being for a nicotinic acetylcholine receptor (pages 17-19 of the specification). Applicant does not teach other radioligand displacement assays that would be required to practice the claimed method, in particular assays directed to "metabolites of interest having pharmacological properties".

In re Wands, 858F.2d 731, 8 USPQ2d 1400 (Fed. Cir. 1988) lists eight considerations for determining whether or not undue experimentation would be necessary to practice an invention. These factors are: the quantity of experimentation necessary, the amount of direction or guidance presented, the presence or absence of

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working examples of the invention, the nature of the invention, the state of the prior art, the relative skill of those in the art, the predictability or unpredictability of the art, and the breadth of the claims.

Applicant provides limited guidance for the method of the instant claims using a radioligand displacement assay as broadly claimed. Applicant only provides guidance for practicing the claimed method using a nicotinic acetylcholine receptor radioligand displacement assay. By nature, the invention requires one of skill in the art to develop a radioligand displacement assay to practice the claimed method. In addition, one of skill in the art must also predetermine what general group of metabolites to assay for, before developing said radioligand displacement assay. The art teaches that binding assays take significant time, and that the properties of potency, activity, specificity and selectivity are separable, such that the presence in a compound of any one property is not predictive of attaining another. The art also teaches that binding assays give no conclusive data on the activity and that the attributes (i.e., agonist activity) are unpredictable and considerable time is added to the discovery program when high affinity compounds identified early in the discovery process turn out to have inappropriate activity or selectivity (see Blume, U.S. Patent Application Publication US 2003/0092057 A1, published 15 May 2003, at page 1, paragraph 0005). Given the limited guidance by Applicant, the nature of the invention and the unpredictability of the art at the time of the invention it would have required undue trial and error experimentation by one of skill in the art to use the invention as broadly claimed. Without significant guidance by Applicant, one of skill in the art would be reduced to

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undue trial and error experimentation in making and using radioligand displacement assay required to use the claimed method, and even then it would require undue trial and error experimentation to determine if the metabolite identified is of any use and if the plant genetic material which has been stimulated by the enhancer-containing DNA is of any use.

See *In re Fisher*, 166 USPQ 18, 24 (CCPA 1970) which teaches "That paragraph (35 USC § 112, first) requires that the scope of the claims must bear a reasonable correlation to the scope of enablement provided by the specification to persons of ordinary skill in the art. In cases involving predictable factors, such as mechanical or electrical elements, a single embodiment provides broad enablement in the sense that, once imagined, other embodiments can be made without difficulty and their performance characteristics predicted by resort to known scientific laws. In cases involving unpredictable factors, such as most chemical reactions and physiological activity, the scope of enablement obviously varies inversely with the degree of unpredictability of the factors involved."

Claim Rejections - 35 USC § 103

14. Claims 1-4 and 6-9 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Fritze *et al* (1995, Methods in Molecular Biology Vol 44, Agrobacterium Protocols, Eds K.M.A. Gartland and M.R. Davey, Humana Press Inc. Totowa, New Jersey, pages 281-294), in view of van der Fits *et al* (2000, Science Vol. 289 14 July, pages 295-297) and in view of Browning *et al* (1982, Br. J. Pharmac. 77:487-491). This rejection is repeated for the reason of record as set forth in the last Office action mailed 15 June

2004. This rejection has been modified in view of Applicant's arguments and amendments to the claims. Applicant's arguments filed 8 September 2004 have been fully considered to the extent that they apply to the instant rejection, but they are not persuasive.

The teachings of Fritze *et al* and Browning *et al* can be found in the previous Office action.

van der Fits *et al* teach a method of identifying a metabolite by T-DNA tagging method by transforming *C. roseus* cells with *Agrobacterium* containing a T-DNA comprising CaMV 35S promoter enhancer sequences (see Figure 2 on page 296). van der Fits *et al* teach analyzing metabolites extracted from 8-day-old cultures (Figure 3 on page 296) and isolating plant genetic material, the action of which had been stimulated by the enhancer-containing T-DNA genetic element in the sample (Figure 2 on page 296).

van der Fits *et al* do not teach using a radioligand displacement assay to identify metabolites in the cultures.

Applicant argues that neither of Fritze *et al* nor Browning *et al* teach or suggest undertaking genetic analysis of calli without disrupting their growth and vitality (page 13 of the Remarks). The Examiner has addressed this argument citing van der Fits *et al* which teaches that it would have been *prima facie* obvious to one of ordinary skill in the art at the time of Applicant's invention to undertake genetic analysis of calli. It remains the Examiner's opinion that it would have been obvious to one of ordinary skill in the art at the time of Applicant's invention to use a gene activation method by T-DNA tagging

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comprising at least one enhancer-containing T-DNA genetic element, and that depending upon the plant used in the method, using a radioligand displacement assay would have also been obvious, especially if a poppy plant was used to develop increased opiate production. Radioligand displacement assays had been widely taught and used by those of ordinary skill in the art at the time of Applicant's invention to assay for opiates, and are understood by those of ordinary skill in the art to be highly sensitive requiring very small samples. Given the teachings of Fritze *et al* and Browning *et al* and van der Fits *et al*, one of ordinary skill in the art at the time of Applicant's invention would have had a reasonable expectation of success in using a radioligand displacement assay to identify callus cultures producing a metabolite whose production is increased in a plant cell by a gene activation method.

Conclusion

15. Claims 10-13 are free of the prior art.
16. Claims 1-4 and 6-9 remain rejected, and claims 10 and 11 are rejected.
17. Claims 12 and 13 are objected to, claim 12 containing a typographical error and claim 13 dependent upon a rejected base claim.
18. No claims are allowed.
19. This Office action is non-final in view of the new grounds of rejection.

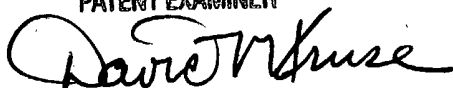
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20. Any inquiry concerning this communication or earlier communications from the examiner should be directed to David H. Kruse, Ph.D. whose telephone number is (571) 272-0799. The examiner can normally be reached on Monday to Friday from 8:00 a.m. to 4:30 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dr. Amy Nelson can be reached at (571) 272-0804. The fax telephone number for this Group is (703) 872-9306 Before Final or (703) 872-9307 After Final.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group Receptionist whose telephone number is (571) 272-0547.

DAVID H. KRUSE, PH.D.
PATENT EXAMINER



David H. Kruse, Ph.D.
22 November 2004

21. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

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